## **Complete Summary**

#### **GUIDELINE TITLE**

ACR Appropriateness Criteria™ for premature cervical dilatation.

## BIBLIOGRAPHIC SOURCE(S)

Laing F, Mendelson E, Bohm-Velez M, Bree RL, Finberg H, Fishman EK, Hricak H, Sartoris D, Thurmond A, Goldstein S. Premature cervical dilatation. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun 1;215(Suppl):939-45. [24 references]

#### **COMPLETE SUMMARY CONTENT**

**SCOPE** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

#### **SCOPE**

#### DISEASE/CONDITION(S)

Premature cervical dilatation (cervical incompetence)

**GUIDELINE CATEGORY** 

Diagnosis

CLINICAL SPECIALTY

Obstetrics and Gynecology Radiology

#### INTENDED USERS

Health Plans Hospitals Managed Care Organizations Physicians Utilization Management

#### GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for premature cervical dilatation (cervical incompetence).

#### TARGET POPULATION

Patients with premature cervical dilatation (cervical incompetence)

#### INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Transabdominal sonography
- 2. Translabial/transvaginal sonography
- 3. Digital examination

#### MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in diagnosis of preterm cervical dilation.

#### METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

#### NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)
Weighting According to a Rating Scheme (Scheme Not Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

#### METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the ACR Board of Chancellors.

#### **RECOMMENDATIONS**

#### MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria™

<u>Clinical Condition</u>: Premature Cervical Dilatation

<u>Variant 1</u>: Patient not at risk for preterm delivery: 18 weeks gestation: by transabdominal scan cervix = 2.5 cm long.

| Radiologic Exam<br>Procedure                             | Appropriateness<br>Rating | Comments |
|--|---------------------------|----------|
| Ultrasound   |                           |          |
| Report Specific Cervical length in mm or cm              | 9                         |          |
| Transbdominal followed by<br>Translabial or Transvaginal | 8                         |          |
| Multiple looks at Cervix<br>during US Exam               | 8                         |          |
| Report Endocervical<br>Diameter in mm (if dilated)       | 8                         |          |
| Transabdominal Scan only –<br>Bladder Full               | 2                         |          |
| Transabdominal Scan only –<br>Bladder Empty              | 2                         |          |
| Single look at Cervix during<br>US Exam                  | 2                         |          |
| Sonographic Cervical Stress<br>Test                      | No Consensus              |          |

Appropriateness Criteria Scale

123456789

1=Least appropriate 9=Most appropriate

<u>Variant 2</u>: Patient at risk for preterm delivery (history of 3 prior midtrimester spontaneous losses): 18 weeks gestation: by transabdominal scan cervix = 3.8 cm long.

| Radiologic Exam<br>Procedure                             | Appropriateness<br>Rating | Comments |
|--|---------------------------|----------|
| Ultrasound   |                           |          |
| Report Specific Cervical length in mm or cm              | 9                         |          |
| Multiple looks at Cervix<br>during US Exam               | 8                         |          |
| Report Endocervical<br>Diameter in mm (if dilated)       | 8                         |          |
| Transabdominal Scan only –<br>Bladder Empty              | 6                         |          |
| Transbdominal followed by<br>Translabial or Transvaginal | 6                         |          |
| Transabdominal Scan only –<br>Bladder Full               | 2                         |          |
| Single look at Cervix during<br>US Exam                  | 2                         |          |
| Sonographic Cervical Stress<br>Test                      | No Consensus              |          |
| Appropriateness Criteria Scale                           |                           |          |
| 1 2 3 4 5 6 7 8 9  |                           |          |
| 1=Least appropriate 9=Most appropriate                   |                           |          |

<u>Variant 3</u>: Patient at no risk for preterm delivery: 18 weeks gestation: by transabdominal scan cervix = 3.8 cm long.

| Radiologic Exam<br>Procedure         | Appropriateness<br>Rating | Comments |
|--------------------------------------|---------------------------|----------|
| Transabdominal Scan only             | 8                         |          |
| Single look at Cervix during US Exam | 8                         |          |
| Report Endocervical                  | 8                         |          |

| Diameter in mm (if dilated)                               |   |  |
|---|---|--|
| Transabdominal followed by<br>Translabial or Transvaginal | 2 |  |
| Sonographic Cervical Stress<br>Test                       | 2 |  |
| Multiple looks at Cervix<br>during US Exam                | 2 |  |
| Report Specific Cervical length in mm or cm               | 2 |  |
|   |   |  |

## Appropriateness Criteria Scale

123456789

1=Least appropriate 9=Most appropriate

<u>Variant 4</u>: Patient not at risk for preterm delivery: 28 weeks gestation: by transabdominal scan cervix = 2.5 cm long.

| Radiologic Exam<br>Procedure                              | Appropriateness<br>Rating | Comments |
|---|---------------------------|----------|
| Ultrasound  |                           |          |
| Report Specific Cervical length in mm or cm               | 9                         |          |
| Transabdominal followed by<br>Translabial or Transvaginal | 8                         |          |
| Multiple looks at Cervix<br>during US Exam                | 8                         |          |
| Report Endocervical<br>Diameter in mm (if dilated)        | 8                         |          |
| Transabdominal Scan only –<br>Bladder Full                | 2                         |          |
| Transabdominal Scan only –<br>Bladder Empty               | 2                         |          |
| Single look at Cervix during<br>US Exam                   | 2                         |          |
| Sonographic Cervical Stress<br>Test                       | No Consensus              |          |

### Appropriateness Criteria Scale

### 123456789

## 1=Least appropriate 9=Most appropriate

<u>Variant 5</u>: Patient at risk for preterm delivery (history of 3 prior midtrimester spontaneous loses): 28 weeks gestation: by transabdominal scan cervix = 3.8 cm long.

| Radiologic Exam<br>Procedure                             | Appropriateness<br>Rating | Comments |  |
|--|---------------------------|----------|--|
| Ultrasound   | Ultrasound                |          |  |
| Report Specific Cervical length in mm or cm              | 9                         |          |  |
| Multiple looks at Cervix<br>during US Exam               | 8                         |          |  |
| Report Endocervical<br>Diameter in mm (if dilated).      | 8                         |          |  |
| Transabdominal Scan only –<br>Bladder Empty              | 6                         |          |  |
| Transbdominal followed by<br>Translabial or Transvaginal | 6                         |          |  |
| Transabdominal Scan only –<br>Bladder Full               | 2                         |          |  |
| Single look at Cervix during<br>US Exam                  | 2                         |          |  |
| Sonographic Cervical Stress<br>Test                      | No Consensus              |          |  |
| Appropriateness Criteria Scale                           |                           |          |  |

123456789

1=Least appropriate 9=Most appropriate

<u>Variant 6</u>: Patient at no risk for preterm delivery: 28 weeks gestation: by transabdominal scan cervix = 3.8 cm long.

| Radiologic Exam Appropriateness Comments |
|--|
|--|

| Procedure   | Rating |  |
|---|--------|--|
| Ultrasound  |        |  |
| Transabdominal Scan only                                  | 8      |  |
| Single look at Cervix during US Exam                      | 8      |  |
| Report Endocervical<br>Diameter in mm (if dilated)        | 8      |  |
| Transabdominal followed by<br>Translabial or Transvaginal | 2      |  |
| Sonographic Cervical Stress<br>Test                       | 2      |  |
| Multiple looks at Cervix<br>during US Exam                | 2      |  |
| Report Specific Cervical length in mm or cm               | 2      |  |

#### Appropriateness Criteria Scale

123456789

1=Least appropriate 9=Most appropriate

#### Summary

#### Digital Examination

Initial assessment is usually clinical and is based on digital palpation of the cervix. Some physicians question the accuracy of digital measurements, which consistently underestimate measurements made by translabial and transvaginal ultrasound.

Nonetheless, if a patient is clinically at risk for preterm delivery, or if the ultrasound examination detects a short cervical length, some obstetrician-gynecologists may perform a digital cervical examination. If she is near term (>37 weeks), however, this examination can be omitted, unless clinically indicated for other reasons. To optimize the results and patient management, it is important to correlate the findings of the ultrasound examination with the digital examination.

#### Sonographic Examination

Unlike digital examination, sonographic measurements of cervical length generates an image that may be reviewed and standardized, thus overcoming subjectivity.

Normal appearing cervix: During pregnancy, the length of the cervix does not elongate appreciably. Most authorities consider 3.0 cm in length as the lower limit of normal.

Transabdominal evaluation: Because most obstetrical examinations are done transabdominally, this method remains the most common, even though it is the least reliable imaging method for evaluating the cervix. Aside from women near term (>37 weeks), if a patient has a clinical history or sonographic findings suspicious for cervical pathology, consideration should be given to additional scanning using either a transperineal or transvaginal approach. Rarely, in an atrisk patient, the entire cervix is clearly visible on a technically adequate transabdominal examination, in which case the translabial/transvaginal scan may be omitted. If a patient is not at risk, and has a normal-appearing cervix on transabdominal scans (with an empty or minimally filled bladder), it is not necessary to proceed to translabial/transvaginal imaging.

Translabial/transvaginal evaluation: These approaches are the most accurate for assessing the cervix. Cervical length is determined as the distance between the internal and external os. The internal os is normally at the level where the cervical canal meets the amniotic sac. The external os is often more difficult to precisely define because of acoustic shadowing from rectal gas. This problem can be minimized by either scanning the patient in a lateral decubitus position, or by elevating the hips and buttocks on a thick pad or pillow. In patients at risk for cervical shortening or incompetence, some investigators suggest performing a cervical "stress test" by either applying transfundal pressure while scanning transvaginally, or by examining the patient while she is standing. Because some patient will initially have a completely normal-appearing cervix, these important maneuvers may identify additional women who may require treatment for preterm cervical dilatation. If the cervix is already dilated or short, the cervical stress test may not be necessary because it may compound the problem by inducing further dilatation and shortening.

Abnormal-appearing cervix: Although the clinical presentation varies, from an imager's point of view cervical changes are essentially identical in patients in term labor, preterm labor, or cervical incompetence. In each of these clinical situations, cervical dilatation begins proximally, at the level of the internal os, and progresses distally. As the internal os dilates, membranes and amniotic fluid invaginate into the proximal endocervical canal. The most accepted terminology for these changes is funneling, although wedging or beaking have also been used. Eventually the entire endocervical canal becomes filled with fluid, and if the membranes remain intact, they may be visible bulging into the vagina. Concurrent with dilatation, the cervix becomes effaced and shortened. Dilatation and effacement typically progress simultaneously, although, in a given patient, one or the other event may appear to predominate.

Investigators have recommended quantitating these cervical changes using a variety of measuring techniques, but the simplest and most reproducible measurement in sensitivity and predictive value appears to be the residual closed length of cervix. This calculation, which takes into account both dilatation and effacement, can be obtained by measuring from the distal apex of endocervical funneling at the internal os to the external os. Analysis by lams and colleagues support 3.0 cm as the optimal cutoff to maximize sensitivity and specificity for

predicting premature delivery. Their investigation showed that all 24 subjects who delivered prematurely had a cervical length of less than 3.0 cm, and none of 15 women who had a cervical length of at least 3.0 cm delivered spontaneously before 36 weeks.

If a woman is clinically at risk for preterm delivery, or if a short cervix is detected by sonography, the precise length of the cervix should be measured and reported (this is usually based on translabial or transvaginal scans). In addition, in cases with visible dilatation, sonologists should report the maximal endocervical diameter. The percent of "effacement" is not reliable based on sonographic images, because it is not possible to determine the location of the internal os once funneling and dilatation begin.

#### Conclusion

Translabial and transvaginal sonography can each provide unique information that can aid sonographic examination of the cervix, and can provide information that otherwise might not be readily available. These examinations are easy to perform, and in the appropriate clinical setting, should become an integral part of the sonographic study.

#### CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

#### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

#### BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Diagnosis of premature cervical dilatation may prevent preterm birth (<37 weeks of gestation).

Subgroups Most Likely to Benefit:

Women who are clinically at risk for preterm delivery.

Women who have been diagnosed with a short cervix as detected by sonography (cervical length of less than 3.0 cm).

#### POTENTI AL HARMS

There is potential for a false diagnosis (false positive) on a transabdominal scan or for a failure to diagnose (false negative) preterm cervical dilatation during transperineal or transvaginal scanning.

Subgroups Most Likely to be Harmed:

A false diagnosis of preterm cervical dilatation may be made on a transabdominal scan in a patient who has a resolving lower uterine segment contraction or whose cervix is vertically oriented (typically with a nondistended maternal bladder), and lacks prominent endocervical mucus. Under these circumstances, the glandular tissue circumferentially surrounding the endocervical canal can appear quite sonolucent and mimic endocervical fluid. These false positive errors can be avoided if a patient with suspicious findings on transabdominal images is reevaluated using a translabial or transvaginal approach. A false diagnosis of preterm cervical shortening may occur on a translabial scan if rectal gas obscured the external os.

False negative diagnoses can occur during transperineal or transvaginal scanning if a cervical stress test is omitted. One of the most challenging groups of patients to evaluate are those in whom the appearance of the cervix changes during the sonographic examination. These transient but important observations underscore the need to observe the appearance of the cervix several times during a single obstetrical sonographic study, and suggest that a single image of the cervix may be insufficient for thorough cervical evaluation. This is particularly the case in women at-risk for preterm delivery, or those in whom a short cervix is detected by sonography. When a woman has transitory cervical changes, the minimal length of residual cervix should be reported and the patient should be considered at risk. Clinical follow-up of these women reveals that 61%-74% have preterm labor or deliver prematurely.

#### QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to quide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

#### IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

#### IDENTIFYING INFORMATION AND AVAILABILITY

#### BIBLIOGRAPHIC SOURCE(S)

Laing F, Mendelson E, Bohm-Velez M, Bree RL, Finberg H, Fishman EK, Hricak H, Sartoris D, Thurmond A, Goldstein S. Premature cervical dilatation. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun 1;215(Suppl):939-45. [24 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999

GUI DELI NE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria™

**GUI DELI NE COMMITTEE** 

ACR Appropriateness Criteria™ Committee, Expert Panel on Women's Imaging.

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Names of Panel Members: Faye Laing, MD; Ellen Mendelson, MD; Marcela Bohm-Velez, MD; Robert L. Bree, MD; Harris Finberg, MD; Elliot K. Fishman, MD; Hedvig Hricak, MD, PhD; David Sartoris, MD; Amy Thurmond, MD; Steven Goldstein, MD

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

An update is in progress at this time. (The ACR Appropriateness Criteria<sup>™</sup> are reviewed after five years, if not sooner, depending upon introduction of new and highly significant scientific evidence.)

#### GUIDELINE AVAILABILITY

Electronic copies: Available (in PDF format) from the <u>American College of Radiology Web site</u>.

Print copies: Available from ACR, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

#### AVAILABILITY OF COMPANION DOCUMENTS

None available

#### PATIENT RESOURCES

None available

#### NGC STATUS

This summary was completed by ECRI on December 28, 2000. The information was verified by the guideline developer on January 25, 2001.

#### COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

Appropriate instructions regarding downloading, use and reproduction of the American College of Radiology (ACR) Appropriateness Criteria<sup>™</sup> guidelines may be found at the American College of Radiology's Web site <a href="www.acr.org">www.acr.org</a>.

## © 1998-2004 National Guideline Clearinghouse

Date Modified: 11/8/2004

HYPERLINK "http://www.firstgov.gov" \t "\_new" FIRSTGOV

